DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-21-21EB; Docket No. ATSDR-2021-0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses." The proposed study will examine the relationship between PFAS serum levels and susceptibility to certain acute viral illnesses, including but not limited to COVID-19.

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2021-0004 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Evaluating the Impact of Per- and Polyfluoroalkyl Substances (PFAS) Exposure on Susceptibility to Viral Infection – New - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per- and poly-fluoroalkyl substances (PFAS) are a large, diverse group of thousands of chemicals. They have been used extensively in a wide range of industrial and consumer applications. Epidemiological studies have evaluated the associations between PFAS exposure and health effects in humans. Evidence from studies in occupationally exposed populations, residential populations exposed to higher levels of PFAS in drinking water, and studies in the general population suggest associations between PFAS and several health outcomes. Exposure to PFAS is nearly ubiquitous in the United States. Epidemiological studies suggest that PFAS exposure may impact the immune system and susceptibility to viral infections; however, there is little consistency in the results of studies on PFAS exposure and infectious disease. The coronavirus disease 2019 (COVID-19) pandemic presents a unique concern and opportunity to explore this association. If PFAS affect the immune system, it is possible that they could affect susceptibility to infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, or could affect severity of COVID-19.

In 2019 and 2020, the Agency for Toxic Substances and Disease Registry (ATSDR) conducted statistically based biomonitoring PFAS exposure assessments (EAs) in eight communities that had documented exposures to PFAS in drinking water. ATSDR also supported two EAs that were designed to test the PFAS Exposure Assessment Technical Tools (PEATT). PFAS concentrations were measured in serum collected from EA and PEATT assessment participants, and a questionnaire was administered to gather information to characterize each individual's exposure. These communities were investigated under "Per- or Polyfluoroalkyl Substances Exposure Assessments [PFAS EAs]" (OMB Control No. 0923-0059, expiration date 06/30/2022).

During the same period, ATSDR initiated a health study at the Pease International Tradeport that included measurement of PFAS serum levels and collection of information about individual exposures in participants under "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS) at Pease International Tradeport, Portsmouth, NH (The Pease Study)" (OMB Control No. 0923-0061, expiration date 08/31/2022).

This a new two-year ATSDR information collection request (ICR) for a collaborative study between the National Center for Environmental Health (NCEH) and ATSDR. This follow-up study will recruit participants who were participated in a previous ATSDR-funded study, who have existing PFAS serum measurements, and who have given prior consent for additional contact from NCEH/ATSDR.

We anticipate that the total number of participants enrolled in the NCEH/ATSDR cohorts will be around 4,075 individuals (3,300 adults and 775 children). This study will attempt to enroll the entire universe of eligible participants; therefore, our target sample size is 4,075. The cohorts have a substantial number of participants with high PFAS exposure, as well as a sufficient range of serum PFAS concentrations to allow examination of associations between the outcomes and across a wide range of PFAS exposures.

The objectives are the following: (1) to examine the association between PFAS concentrations in serum collected from existing ATSDR cohorts and the frequency of occurrence of selected syndromes (combinations of self-reported symptoms), which will be used as a proxy for viral infections; and, (2) to examine the association between PFAS concentrations in serum collected from existing ATSDR cohorts and self-reported positive test results indicating specific viral infections.

During the first three months of the two-year study period, NCEH/ATSDR will invite and consent approximately 4,075 participants (3,300 adults and 775 children) to complete a new series of questionnaires to determine whether PFAS exposure increases susceptibility to viral infections, including, but not limited to, COVID-19. Data will be collected from those who enroll in the study through an initial paper-based questionnaire and a series of four additional questionnaires over a 12- to 14-month period. Follow-up questionnaires will be offered in two

modes: web-based and paper-based. It is estimated that 75 percent of the participants will choose the web-based mode. Participants will also be given symptom diaries to improve recall after the initial and between each of the follow-up questionnaires.

The total time burden requested is 12,724 hours annually. There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Annual Burden (in hr)
Adults	Initial Questionnaire - Adult (paper)	1650	1	30/60	825
	Follow up Questionnaire - Adult (paper)	412	4	30/60	825
	Follow up Questionnaire - Adult (REDCap)	1238	4	25/60	2063
	Symptom Diary	1650	1	4	6600
Children (7-17 years)	Initial Questionnaire - Child (paper)	290	1	30/60	145
	Follow up Questionnaire - Child (paper)	72	4	30/60	145
	Follow up Questionnaire - Child (REDCap)	218	4	25/60	363
	Symptom Diary	290	1	4	1160
Parents of Children	Initial Questionnaire	75	1	30/60	38

(3-6 years)	- Child (paper)				
	Follow up Questionnaire - Child (paper)	24	4	30/60	49
	Follow up Questionnaire - Child (REDCap)	74	4	25/60	123
	Symptom Diary	98	1	4	390
Total					12,724

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2021-06882 Filed: 4/2/2021 8:45 am; Publication Date: 4/5/2021]